



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/712,966

11/12/2003

Charles H. Pugsley

81614A

9418

7590

08/28/2006

KRIEGSMAN & KRIEGSMAN

665 Franklin Street

Framingham, MA 01702

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/712,966 | Applicant(s) PUGSLEY ET AL. | |
| | Examiner Julian W. Woo | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/12/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-13 is/are allowed.
- 6) ☒ Claim(s) 1-8, 14-19 and 21 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/12/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Sander et al. (5,522,817). Sander et al. disclose, at least in figure 2 and in col. 2, line 65 to col. 3, line 64 and col. 4, lines 32-45; a biocompatible fastener includes a first portion or member and a second portion or member, where the first portion or member (203) is made out of a first bioabsorbable material, and the second portion or member (201) is made out of a non-bioabsorbable material, where the first portion is coated over a portion of the second portion (at the interface between 202 and 204), where the first portion is degradable and can result in fragmentation of the fastener; where the fastener comprises a male member (203) with a post and a head (at 204), and the female member (201) includes bore and a flange extending into the bore (at 202).

3. Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandewalle (6,022,352). Vandewalle disclose, at least in figures 2, 3, and 8 and in col. 3, line 27 to col. 4, line 8; a biocompatible fastener includes a first portion or sleeve and a second portion or inner core, where the first portion (46) or outer coating is made out of a first bioabsorbable material, and the second portion (50) or inner core is made out of a non-bioabsorbable material, where the fastener comprises male and female

Art Unit: 3731

members, where the male member (50) includes a post (54) and a head (56), and the female member (46) defines a bore and a flange (an internal thread) extending into the bore.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 14-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luscombe et al. (5,258,012) in view of Jarrett et al. (5,080,665). Luscombe et al. disclose, at least in the figures and in col. 7, lines 18-35, a biocompatible fastener (50) including a male portion (52) with a first base member (54) and first and second male members (56), each including a post and a head (58) with a generally conical, sharp tip; and a female portion (80) comprising a second base member (82) and first and second sleeves (84), each sleeve defining a bore (86) and a flange (90) extending into the bore; where the first and second base members are each generally flat and oval (see figs. 4

Art Unit: 3731

and 12), where the first sleeve includes a pair of longitudinal slots (between elements 90 in each bore), where the flange is made of a first bioabsorbable material, and the first base member comprises a second bioabsorbable material. However, Luscombe et al. do not disclose that the second bioabsorbable material has a degradation rate slower than the degradation rate of the flange. Jarrett et al. teach, at least in col. 7 lines 1-22, that the choice of bioabsorbable materials (and hence, their degradation rates) depends on the desired physical properties of the surgical devices. Thus, it would have been a matter of obvious design choice to apply a second bioabsorbable material that has a degradation rate slower than the degradation rate of the flange in the device of Luscombe et al. The choice would be dependent upon the desired stiffness, as well as the degradation rates, of the components of the fastener.

Allowable Subject Matter

6. Claims 9-13 are allowed.

7. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a biocompatible fastener including, inter alia, a sleeve with a bore and a flange in the bore and a male member with post and a head, where at least one of the flange and the head includes a outer coating material that is a first bioabsorbable material with a first degradation rate and an inner core material that is nonbioabsorbable or a second bioabsorbable material.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

8. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a biocompatible fastener including a male portion with a first base member and a first male member including a post and a head, and a female portion comprising a second base member and a first sleeve, where at least one of the flange and the head is at least partially made of first bioabsorbable material, at least one of the first and second base members comprises a non-bioabsorbable material or a second bioabsorbable material, and where the first sleeve has a top end shaped to terminate in a relatively sharp tip.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Green et al. (4,932,960) teach a biocompatible fastener.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

Art Unit: 3731

4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

August 21, 2006